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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Pathak et al. January 10, 2002

Predecesosr Serial No.: 09/411,764 Predecessor Group Art Unit No.: 1615

Predecessor Filing Date: October 4, 1999 Predecessor Examiner: Amy Pulliam

For: Formulations, Tablets of Paroxetine and Process to Prepare Them

Assistant Commissioner for Patents  
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Preliminarily to the examination of this application, please enter the following amendments and remarks into the record.

Please delete the title and replace it with "Formulations, Tablets of Paroxetine and Process to Prepare Them".

Please delete claims 1-15. Please add claims 16 and 17.

16. A pharmaceutical composition in tablet form containing paroxetine, produced on a commercial scale by a process which comprises the steps of:

a) dry admixing paroxetine and excipients in a mixer to form a mixture; or

b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and

c) compressing the mixture into tablets;

provided that one of the excipients is not microcrystalline cellulose.

17. A pharmaceutical composition in tablet form according to claim 16 containing an amount of paroxetine selected from: 10 mg, 20 mg, 30 mg, 40 mg and 50 mg, wherein the amount of paroxetine is expressed as the free base, produced on a commercial scale by a process which comprises the steps of:

- a) dry admixing paroxetine and excipients in a mixer to form a mixture; or
- b) dry admixing paroxetine and excipients, compressing the resulting combination into a slug material or roller compacting the resulting combination into a strand material, and milling the prepared material into a free flowing mixture; and
- c) compressing the mixture into tablets using a single punch or rotary tablet machine;

provided that one of the excipients is not microcrystalline cellulose.

REMARKS

Applicants respectfully request examination of the instant application as amended herein. The instant amendments are made to eliminate multiple dependent claims and put the application in better form for examination. Please add the enclosed Abstract as the Abstract in this application.

If any matters remain to be resolved before search, examination and allowance, or discussion of any matter will facilitate the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicates below.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Applicants note that all of the previously pending claims have been deleted and replaced by a new claim set. As such, a marked-up version of the claims is not necessary.